K072392

510(K) SUMMARY
FOR THE
OPDIMA

SEP 25 2007

Submitted by:

Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

August 23, 2007

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. Contact Person:

Ms. Kim Rendon
51 Valley Stream Parkway
Malvern, PA 19355
Phone: (610) 448-1773
Fax: (610) 448-1787

2. Device Name and Classification:

Trade Name:	OPDIMA Digital Mammographic X-ray System
Classification Name:	Mammographic X-Ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1710
Device Classification:	Class II
Product Code:	90IZL

3. Substantial Equivalence:

The OPDIMA is substantially equivalent to the following devices:

Predicate Device Name	*510(k) Number*	*Clearance Date*	*Comparable Properties*
OPDIMA Digital Mammographic X-ray system	K003945	02/02/2001	• Hardware • Control Software • Image processing • Intended use
OPDIMA Digital Mammographic x-ray system	K071015	05/10/2007	• Control Software • Image processing • Intended use

4. Device Description:

OPDIMA is a Small Field Digital Mammography (SFDM) system. It is marketed as an option to the Siemens MAMMOMAT Novation X-ray examination system. It provides spot imaging for diagnosis and stereotactic biopsy. OPDIMA features a small (49 x 85 mm^2) CCD detector that converts the X-ray attenuation into an electronic pattern. The electronic pattern is read out, processed, and displayed on a high resolution monitor. The images may be post processed, printed, or transferred via DICOM network for multiple purposes.

5. Intended Use of the Device:

The Siemens MAMMOMAT series with OPDIMA option is intended for use in small field mammographic X-ray imaging. Such small field imaging is used during stereotactic biopsy and diagnostic spot localization.

6. Technology Characteristics of the principle Device Compared to the Predicate:

The OPDIMA functionality, the technology characteristics of the system, with the new Windows based workstation remain unchanged for the imaging characteristics. Graphical user interface and performance will improve to keep pace with the technology leap. The imaging area (49x85mm^2) remains the same. The maximum resolution (high res mode 2048 x 3584 pixel) with 20 lp/mm and with 13 lp/mm (normal res mode 1024 x 1792 pixel) remains unchanged. Device dependent image processing remains unchanged. Each software module that is reused in the new Windows based workstation is converted to the Windows environment.

The OPDIMA software will run on the AWS of the MAMMOMAT Novation as an additional software module. The FFDM functionality will be disabled while the OPDIMA is in use.

7. General Safety and Effectiveness Concerns

Instructions for use are included within the device labeling and the information provided will enable the trained healthcare professional to operate the device in a safe and efficacious manner. Furthermore the operators are health care professionals familiar with and responsible for the X-ray examination to be performed.

8. Substantial Equivalence

It is the opinion of Siemens Medical Solutions USA, Inc. that the information provided establishes that the OPDIMA when used an option with the MAMMOMAT Novation^{DR} Acquisition Workstation with Windows, is substantially equivalent to the commercially

available OPDIMA with UNIX workstation (K003945) and the OPDIMA with Windows workstation (K071015).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 25 2007

Ms. Kim Rendon
Regulatory Technical Specialist
Siemens Medical Solutions USA, Inc.
51 Valley Stream Pkwy, MS E50
MALVERN PA 19355

Re: K072392
Trade/Device Name: OPDIMA
Regulation Number: 21 CFR 892.1710
Regulation Name: Mammographic x-ray system
Regulatory Class: II
Product Code: IZL
Dated: August 23, 2007
Received: August 27, 2007

Dear Ms. Rendon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K072392

Device Name: **OPDIMA**

Indications for Use:

The Siemens MAMMOMAT series with OPDIMA option is intended for use in small field mammographic X-ray imaging (SFDM). Such small field imaging is used during stereotactic biopsy and diagnostic spot localization.

Prescription Use ___X___ OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072392

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